IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):   Thomas D. Doerr et al.
Serial No.:   09/888,532
Filed: June 25, 2001
For: PHYSICIAN DECISION SUPPORT SYSTEM WITH RAPID DIAGNOSTIC CODE IDENTIFICATION
Examiner: Rines, Robert D.
Art Unit: 3626
Docket No.:   951130.90011

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
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Sir:

Appellant, having filed a timely Notice of Appeal of a Final Office Action in the above-identified patent application, hereby submits this Appeal Brief in support of patentability.

I. REAL PARTY IN INTEREST

The present application is assigned to US-RX, doing business as Wellinx, which is currently doing business as Purkinje, as evidenced by the assignment filed with the USPTO on June 25, 2001, which was recorded June 25, 2001 at Reel/Frame 011948/0780.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-21 are pending in the present application of which claims 1, 7, 10-12, 15, and 17-21 have been finally rejected under 35 U.S.C. §102(b) and claims 2-6, 8, and 9 have been finally rejected under 35 U.S.C. §103(a).

IV. STATUS OF AMENDMENTS

No amendments were submitted by Appellant after the Final Office Action of October 5, 2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to a patient-side decision support system (10). *See* ¶ [0038]. The system (10) includes a hand-held terminal (14) usable during an examination and providing a display (22) and user input device (20, 22, 24). *See* ¶¶ [0009] and [0038]-[0044]. The system (10) also includes a terminal server (30, 32, 34, 36, 38) communicating with the hand-held terminal (14) and holding medical information related to medical diagnoses as linked to a set of diagnosis codes (126). *See* ¶¶ [0009], [0038]-[0044], and [0063]-[0072]. The terminal server (30, 32, 34, 36, 38) executes a stored program to accept from the user input device (20, 22, 24) of the hand-held terminal (14), input designating a methodology producing a subset of the diagnoses codes (126), and present on the display (22) of the hand-held terminal (14) a navigation menu a representation of the subset of the diagnosis codes (126) generated using the selected methodology. *Id*. The terminal server (30, 32, 34, 36, 38) also executes the stored program to accept from the user input device (20, 22, 24) of the hand-held terminal (14) a selection of a particular diagnosis code (126) from the subset, whereby a comprehensive set of diagnosis codes (126) are presented to the physician on a hand-held device at the time and location of patient examination. *Id*.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the final Office Action of October 5, 2006, a variety of objections and rejections were removed in light of previously-presented amendments. However, the Office Action maintained the rejection of claims 1, 7, 10-12, 15, and 17-21 under 35 U.S.C. §102(b) as being anticipated by Evans (U.S. Pat. No. 5,924,074). Additionally, the final Office Action maintained the rejection of claims 2-6 and 8-9 under 35 U.S.C. §103(a) as being unpatentable over Evans in view of Abbo (U.S. Pat. Application No. 2003/0195774). Furthermore, the final Office Action maintained the rejection of claim 16 under 35 U.S.C. §103(a) as being unpatentable over Evans in view of Abbo and in further view of Rappaport (U.S. Pat. Application No. 2002/0007285). Finally, claims 13 and 14 were rejected under 35 U.S.C. §103(a) as

being unpatentable over Evans in view of Abbo and in further view of Mayaud (U.S. Pat. No. 5,845,255).

VII. ARGUMENT

Claims 1, 7, 10-12, 15, and 17-21 rejected under 35 U.S.C. §102(b) as being anticipated by Evans (U.S. Pat. No. 5,924,074).

Regarding claim 1, the Examiner stated that Evans teaches accepting "input designating a methodology producing a subset of diagnoses codes" in column 11, lines 40-52 and presenting "a navigation menu a representation of the subset of the diagnosis codes generated using the selected methodology" in column 6, lines 40-55 and column 11, 30-40. However, the cited sections do not teach or suggest *designating a methodology* to produce a *subset of diagnoses codes* or presenting a navigation menu of the *diagnosis codes* generated using the *designated methodology*. To the contrary, Evans, in the very sections cited by the Examiner, merely teaches that a *diagnosis* can be entered by inputting a *body system* from a list thereof. This is very different from and unrelated to the express purposes of the claimed invention.

In particular, as stated in the present application, "The invention provides *several alternative methodologies* by which the physician may zero in on specific diagnosis codes with minimum effort" so that "diagnostic code information may be captured in a manner that is neither disruptive nor disadvantageous to the individual practitioner." Specification, ¶ [0008] (emphasis added). To this end, the present invention is specifically designed for aiding physicians and clinicians to "improve their medical practice through observing their patient's response to treatments and conferring with their colleagues about the experiences of their colleague's patients." Specification, ¶ [0003]. This process, called "outcome-based" medicine, is facilitated and expanded by the present invention by providing a highly flexible system for record keeping that "tracks diagnoses and outcomes for different treatments so that many physicians can share this data." *Id*. In particular, as explained in the specification,

> Unfortunately it is not a simple matter to collect such records. Physicians are under great time pressure, and stopping to enter data is disruptive to their workflow. Further, entering accurate information requires the physician to choose among some 15,000 to 26,000

possible diagnosis codes and thousands of drug treatments and treatment regimes. This is an impractical burden.

Physicians and their staff have no practical, meaningful incentives to code accurately. They have financial incentives to select diagnosis codes that are likely to win easy reimbursement from payers, and they have very vague threats of regulatory persecution if their codes do not match their office visit patient records. Consequently, at present many physicians delegate the task of diagnosis coding to medical assistants who lack formal training in this area. Over time, medical assistants tend to create and select from a small pool of diagnosis codes that, in their experience, have resulted in hassle-free reimbursement from payers.

Accordingly, most outcome-based systems collect relatively coarse and inaccurate diagnosis data and rely heavily on prescription data from which diagnoses are deduced. These systems are particularly prone to inaccuracy for prescribed drugs that are used for treatment in multiple different diagnoses. Inaccurate diagnosis information can obscure important conclusions about treatment efficacy.

Specification, ¶ [0005] to ¶ [0007].

Therefore, though not appreciated in the Office Action, the present invention, which includes **designating a methodology** to present a navigation menu of a **subset of diagnoses codes**, is different from the cited prior art system for entering a **body system** in order to generate a list of **diagnoses codes** from which to select. That is, the present invention provides a wide degree of flexibility that encourages the physician to select a correct diagnosis code. Evans only allows a physician to receive a subset of diagnoses codes based on a single methodology: body part selection. Hence, Evans cannot be said to teach or suggest designating a methodology for selecting a subset of diagnoses codes because it would clearly be unnecessary to select a methodology when only one methodology is possible. Evans simply does not contemplate or even suggest the flexibility called for in claim 1 that allows a physician to not only limit the diagnoses codes that are displayed but to allow the physician to select the particular methodology for limiting the diagnoses codes.

In response to these arguments, the Examiner stated that the "Examiner interprets Evans' 'selection of a body system' as equivalent to Applicant's 'selecting a methodology.'" Office Action of October 5, 2006, pg. 12. The Examiner provided no support for such an interpretation and Appellant believes that none exists.

In the very sections cited by the Examiner to support the proffered rejection, Evans states:

> For example, to enter a diagnosis, a physician clicks on the scroll down button 331 adjacent to the system box 332 to produce a list of body systems. The physician selects the appropriate system and the diagnosis module 300 enters the selected system in the system box 332 and provides a list having specific diagnosis codes for the selected body system in the diagnosis box 334. The physician then selects the appropriate diagnosis code and clicks on the add button 336 adjacent to the diagnosis selection box 337. The diagnosis module 300 enters the selected diagnosis code to the diagnosis selection box 337. The physician may repeat the above steps to add multiple diagnosis codes to the diagnosis selection box 337.

Col. 11, ll. 40-52.

On the other hand, as described above, claim 1 calls for *designating a methodology* to present a navigation menu of a subset of *diagnoses* codes. The present application describes the entry of a "methodology" in detail and is clear that it is not "equivalent" to the mere entry of a body part, as the Examiner contends. In particular, the specification states, "The invention provides several alternative methodologies by which the physician may zero in on specific diagnosis codes with minimum effort." ¶ [0008]. Paragraphs [0011] through [0018] of the present invention list some of the various methodologies that can be selected to present the navigation menu of a subset of diagnoses codes. Specifically, the examples include:

> The methodology may provide a subset of the most frequently used diagnosis codes for a predetermined set of physicians as the subset of diagnosis codes, for example those physicians practicing a common specialty.
> Thus it is another object of the invention to provide a subset of diagnosis codes limited to those likely to be encountered by a given physician based on his or her general practice.
> Alternatively, the methodology may provide a subset of diagnosis codes indicating the most frequently used diagnosis codes for the user-physician.
> Thus it is another object of the invention to provide a subset of diagnosis codes limited to those likely to be encountered by a given physician based on his or her specific practice.
> The methodology provides most recent diagnosis codes for the patient.
> Thus it is another object of the invention to provide a subset of diagnosis codes specific to a patient and thus likely relevant to a particular patient visit.

Alternatively, the methodology may provide a hierarchy having at least one level of diagnosis code groupings holding a predetermined set of related diagnosis codes that may be selected by the user to reveal the subset of diagnosis codes.

Thus another object of one version of the invention is to provide an arrangement of diagnosis codes that allow rapid access of individual codes through a limited number of hierarchical screens.

¶¶ [0011]-[0018].

Hence, as the specification is clear that the inputting of a methodology is not the mere selection of a body part, as taught by Evans, but the selection of a specific method from a plurality of methods by which the physician would like the diagnostic codes to be limited to a particular subset. Hence, as illustrated by the above-listed variety of possible methodologies contemplated, the present invention provides a flexibility of which Evans makes no teaching or suggestion. To the contrary, Evans is clear that the only method through which a particular subset of diagnostic codes can be selected is by selecting a body part. *See* col. 11, ll. 40-52. One of ordinary skill in the art will readily recognize that Evans cannot be said to teach or suggest the ability to **designate a methodology** to present a navigation menu of a subset of diagnoses codes because Evans only teaches one methodology (selection of body parts). Furthermore, as will be addressed below with respect to a few selected dependent claims, the Examiner apparently recognized this inconsistency with the proffered interpretation and, therefore, sought additional art with which to combine with Evans.

Therefore, the Examiner's statement that the "Examiner interprets Evans' 'selection of a body system' as equivalent to Applicant's 'selecting a methodology'" is improper and cannot be sustained. Office Action of October 5, 2006, pg. 12. For at least the reasons addressed above, claim 1 is patentably distinct from the art of record. Accordingly, claims 2-21 are in condition for allowance at least pursuant to the chain of dependency.

Claims 2-6 and 8-9 rejected under 35 U.S.C. §103(a) as being unpatentable over Evans in view of Abbo (U.S. Pat. Application No. 2003/0195774).

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. MPEP § 2142. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984)*. Accordingly, to establish a *prima facie* case of obviousness, the Examiner must not only show that the combination includes each and every element of the claimed invention, but also provide "a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)*. That is, "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." MPEP § 2143.01.

In the case at hand, Appellant believes that a *prima facie* case of obviousness has not been made based on the art of record because, as will be shown below, (1) the references are directed to very different purposes and there is no motivation to combine these references in the way done so by the Examiner, other than Appellant's own teaching; (2) the combination would not have a reasonable expectation of success; and (3) all of the elements of the present claims are not present in the references. The Examiner has not established the three basic criteria required under MPEP § 2143 and; thus, favorable consideration is respectfully requested.

Regarding claim 2, the Examiner acknowledged that "Evans does not teach the retrieval of the most frequently used diagnostic codes for a predetermined set of physicians." Office Action of October 5, 2006, pg. 6. As addressed above, Appellant agrees with this acknowledgment and asserts that it is inconsistent with the rejection asserted against claim 1. Nevertheless, in an attempt to overcome this shortcoming of Evans, the Examiner cited Abbo, specifically, paragraph [0058]. However,

paragraph [0058] and Abbo as a whole is not supportive of the rejection. To the contrary, Abbo, in the cited section, simply states, "The physician may also have the option of displaying and selecting from a list of common diagnoses used in the particular physician's office, *which are associated with a specified organ system of the body* (e.g., such as musculo-skeletal, cardiovascular, skin disorders, gastrointestinal, etc.)." (Emphasis added). Hence, Abbo does not teach common codes *for a **predetermined set of physicians*** but common codes ***associated with a specified organ system of the body***. One of ordinary skill in the art will readily recognize that these are very different and provide very different functionality. Therefore, claim 2 is further distinguishable from the art of record.

In fact, claim 3 further illustrates this distinction. The Examiner again cited [0058] of Abbo to support the rejection of claim 3. Claim 3 calls for "wherein the predetermined set of physicians is physicians practicing a common specialty." As show above, Abbo only teaches displaying a list of common diagnoses "***which are associated with a specified organ system of the body*** (e.g., such as musculo-skeletal, cardiovascular, skin disorders, gastrointestinal, etc.)." ¶ [0058]. This is not the same as physicians practicing a common specialty, as called for in claim 3. Rather, Abbo teaches a very similar system to that taught by Evans. Specifically, diagnostic code listings that, at best, are divided into subsets based on body parts. Therefore, for the reasons stated above with respect to claims 2 and 3, as well as the reasons set forth with respect to claim 1, the claimed invention is patentably distinct from the art of record and the proffered rejection must be withdrawn.

Similarly, the Examiner cited paragraph [0058] of Abbo when rejecting claim 4, which, in part, calls for "wherein the methodology provides the most frequently used diagnosis codes for the user." As addressed above with respect to claims 2 and 3, Abbo and, in particular, paragraph [0058] simply teaches displaying a list of common diagnoses "***which are associated with a specified organ system of the body***." Nowhere does the art of record teach the selection of a methodology for receiving a subset of diagnostic codes based on most frequently used diagnostic codes for the current user. Hence, claim 4 is further distinguishable from the art of record.

Regarding claim 5, which, in part, calls for "wherein the methodology provides most recent diagnosis codes for the patient," the Examiner cited paragraph [0057] of *Abbo. At best, the most relevant portion paragraph [0057] states, "With respect to*

the diagnosis step, the physician can select a diagnosis from the patient's previous diagnoses (e.g., from a file that includes the patient's major diagnoses) or the physician can enter a new diagnosis." First sentence of ¶ [0057]. However, one of ordinary skill in the art will readily recognize that this statement does not teach or suggest the claimed invention. Specifically, claim 5 calls for the methodology to provide the "*most recent diagnosis codes for the patient*" and not "*the patient's previous diagnoses (e.g., from a file that includes the patient's major diagnoses)*." That is, the claimed invention calls for the diagnoses codes to be limited to 1) the patient and 2) the most recent codes associated with the patient. On the other hand, Abbo teaches that the diagnoses codes are limited to 1) the patient and, optionally, 2) major diagnoses. Hence, Abbo teaches that prior diagnoses, at best, are limited to "major diagnoses" and not to the "most recent," as called for in claim 5. One of ordinary skill in the art will recognize that the claimed invention provides a very different functionality from that which is taught or suggested by Abbo. Therefore, claim 5 is patentably distinct from the art of record above and beyond the chain of dependency.

These arguments presented with respect to the above-addressed dependent claims further exemplify the shortcomings of the rejection presented with respect to claim 1 and the fact that claim 1 is patentably distinct from the art of record. Furthermore, these arguments are exemplary of the fact that, although the dependent claims are in condition for allowance pursuant to the chain of dependency, the dependent claims include additional subject matter that is not taught or suggested by the art of record.

Claims 13 and 14 were rejected under 35 U.S.C. §103(a) as being unpatentable over Evans in view of Abbo and in further view of Mayaud (U.S. Pat. No. 5,845,255).

When addressing claims 13 and 14, the Examiner acknowledged that neither Evans nor Abbo taught or suggested the claimed system for providing "a set of prewritten prescriptions prepared by a team of specialists" (claim 13) or "a set of prewritten prescriptions being the most frequently used prescription by the user for the selected diagnosis code" (claim 14). Office Action of October 5, 2006, pgs. 10 and 11. Accordingly, the Examiner cited Mayaud. However, Appellant asserts that

Mayaud cannot be properly combined with Evans or Abbo and, even if combined, fails to teach or suggest the claimed invention.

Mayaud is directed to a "prescription management system." Title of Mayaud. On the other hand, as acknowledged by the Examiner, neither Evans nor Abbo includes any teaching or suggestion of including the claimed abilities with respect to prescriptions. Rather, as addressed above, Evans and Abbo are directed to medical practice/records management, specifically, using diagnostic codes. Mayaud does not teach or suggest the use of diagnostic codes. In this regard, while Appellant recognizes that prescription medicines and the need to order and prepare prescriptions are often a part of the practice and record keeping of medicine, Appellant believes that the art of record does not support the proffered combination. That is, there is no teaching or suggestion within the art of record and the Examiner has not provided evidence that one of ordinary skill in the art would otherwise be inclined to combine an electronic medical practice/records management with an electronic prescription management system. To the contrary, Appellant asserts that the lack of any teaching or suggestion to include prescription-related capabilities in the systems of Evans and Abbo and the lack of any teaching or suggestion to include general medical practice/records management features in the system of Mayaud indicates that the required motivation is, in fact, lacking. This is particularly true given the traditional interrelation between the practice of medicine and the ordering/preparation of prescriptions. Appellant contends that it is only using the impermissible hindsight gained by Appellant's own disclosure that the proffered combination was yielded.

For at least these reasons, claims 13 and 14 are further distinguishable from the art of record. These arguments presented with respect to the above-addressed dependent claims further exemplify the shortcomings of the rejection presented with respect to claim 1 and the fact that claim 1 is patentably distinct from the art of record. Furthermore, these arguments are exemplary of the fact that, although the dependent claims are in condition for allowance pursuant to the chain of dependency, the dependent claims include additional subject matter that is not taught or suggested by the art of record.

VIII. CONCLUSION

In view of the above, Appellant requests reversal of the final rejection regarding claims 1-21 and a Notice of Allowance.

Respectfully submitted,

Dated: February _8_, 2007   By: _____

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APPENDIX A
Claims of Patent Application No. 09/888,532

1.   (Original) A patient-side decision support system comprising:

a hand-held terminal usable during an examination and providing a display and user input device;

a terminal server communicating with the hand-held terminal and holding medical information related to medical diagnoses as linked to a set of diagnosis codes, the terminal server further executing a stored program to:

(a) accept from the user input device of the hand-held terminal, input designating a methodology producing a subset of the diagnoses codes;

(b) present on the display of the hand-held terminal a navigation menu a representation of the subset of the diagnosis codes generated using the selected methodology;

(c) accept from the user input device of the hand-held terminal a selection of a particular diagnosis codes from the subset; and

whereby a comprehensive set of diagnosis codes can be present to the physician on a hand-held device at the time and location of patient examination.

2.   (Original) The patient-side decision support system of claim 1 wherein the methodology provides the most frequently used diagnosis codes for a predetermined set of physicians as the subset of diagnosis codes.

3.   (Previously Presented) The patient-side decision support system of claim 2 wherein the predetermined set of physicians is physicians practicing a common specialty.

4.   (Original) The patient-side decision support system of claim 1 wherein the terminal server further executes the stored program to accept from the user input device of the hand-held terminal, input identifying the user, and wherein the methodology provides the most frequently used diagnosis codes for the user.

5.   (Original) The patient-side decision support system of claim 1 wherein the terminal server further executes the stored program to accept from the user input

device of the hand-held terminal, input identifying a patient, and wherein the methodology provides most recent diagnosis codes for the patient.

6. (Original) The patient-side decision support system of claim 1 wherein the terminal server further executes the stored program to accept from the user input device of the hand-held terminal, input identifying a patient, and wherein the methodology provides diagnosis codes previously selected for the user that have not been removed by editing.

7. (Original) The patient-side decision support system of claim 1 wherein the methodology provides a hierarchy having at least one level of diagnosis code groupings holding a predetermined set of related diagnosis codes that may be selected by the user to reveal the subset of diagnosis codes.

8. (Previously Presented) The patient-side decision support system of claim 7 wherein the terminal server further executes a stored program to provide the user with the ability to search for a specific diagnosis code by name of the diagnosis code.

9. (Previously Presented) The patient-side decision support system of claim 1 wherein the terminal server further executes a stored program to provide the user with the ability to search for a specific diagnosis code by name of the diagnosis code.

10. (Original) The patient-side decision support system of claim 1 wherein the diagnosis codes are ICD-9 codes.

11. (Original) The patient-side decision support system of claim 1 wherein the terminal server further includes a table selecting only a subset of the ICD-9 codes to include in the set of diagnosis codes selectable by the user.

12. (Original) The patient-side decision support system of claim 1 wherein the terminal server further executes a stored program to:
(d) provide to the user the medical information linked to the selected diagnosis codes.

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13.   (Original) The patient-side decision support system of claim 1 wherein the terminal server further executes a stored program to provide to the user a set of prewritten prescriptions prepared by a team of specialists.

14.   (Original) The patient-side decision support system of claim 1 wherein the terminal server further executes the stored program to accept from the user input device of the hand-held terminal, input identifying the user, and wherein the methodology provides a set of prewritten prescriptions being the most frequently used prescription by the user for the selected diagnosis code.

15.   (Original) The patient-side decision support system of claim 1 wherein the medical information is selected from the group consisting of relevant treatment options, patient handouts, and physician education information.

16.   (Original) The patient-side decision support system of claim 1 wherein the diagnosis codes of the displayed subset is hyperlinked to a description of the diagnosis code

17.   (Previously Presented) The patient decision support system of claim 16 wherein the display provides a resolution of at least 600 by 200 pixels.

18.   (Original) The patient decision support system of claim 1 wherein the hand-held terminal provides a wireless link communicating with the terminal server.

19.   (Original) The patient decision support system of claim 1 wherein the physician input device is selected from a keyboard and stylus entry device.

20.   (Original) The patient decision support system of claim 1 wherein the display is a graphic display providing for the display of text and images.

21.   (Previously Presented) The patient decision support system of claim 1 wherein the terminal server and the hand-held terminal provide interfaces connecting

to the Internet and wherein the terminal server connects with the hand-held terminal via the Internet.

APPENDIX B
EVIDENCE

There is no evidence, other than the documents cited in the final Office Action.

APPENDIX C

RELATED PROCEEDINGS

There are no decisions in related proceedings.